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RE: Application # 10/675,722



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Invention: Biodegradable Wound Dressing

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This application is crossed referenced to Provisional Application Number 60/414,255

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There is no Federal Funding associated with any aspect of this invention

SPECIFICATION

1 *BACKGROUND OF THE INVENTION*

2 Wound healing presents a challenge to medical and surgical personnel. This is particularly true
3 with large wounds having poorly defined edges; for example, burns, decubitus ulcers, venous
4 stasis ulcers, arterial ulcers and serious abrasions. Wounds are often treated by covering them
5 with products such as alginates, composites, contract layers, foams, hydrocolloids, hydrogels,
6 impregnated gauzes, specialty absorptive, and transparent films. The theory behind the use of
7 these products is that covering the wound decreases the risk of infection, keeps the wound from
8 drying out, and decreases scarring.

9 Other products have been introduced which theoretically increase the rate of wound healing.

10 Examples include topical cleansers, sealants, protectants, moisturizers, and enzymatic debriding
11 agents. More recently, biological and biosynthetic dressings impregnated with collagen or related
12 hydrolysates have been introduced. The theory behind these agents is that the collagen contained
13 within the dressings mimics the natural collagen produced by the body and, thereby, promotes

1 healing. Without treatment secreting skin wounds may lead to anemia, infections, shock and
2 even death through the loss of body proteins, electrolytes, fluids and heat.
3 However, all of these approaches have shortcomings related to absorption characteristics and
4 capacities, wound cleaning efficiency, discomfort in application and removal, bacterial
5 susceptibility, expense and, in many cases, disposal problems. The proposed biodegradable
6 starch foam dressing addresses and eliminates many of these shortcomings providing a self
7 assembling gel barrier, which absorbs large quantities of exudates, maintains appropriate levels
8 of hydration and allows body movement without restraint.

9 *SUMMARY OF THE INVENTION*

10 A hydrophilic pliable wound dressing consisting of biopolymers provides a self-assembling
11 hydrophilic gel serving as a moisture permeable barrier applicable to a wide range of wound
12 sizes and depths. Biodegradability and water solubility enable rapid and safe disposal, obviating
13 a significant problem that occurs with conventional type dressings. The initial sheet form of the
14 dressing provides an ideal carrier for delivery of nutrients, enzymatic debriders antibiotics,
15 analgesics, physiological regulators and other bio-molecules.

16 *BRIEF DESCRIPTION OF THE DRAWINGS*

17 The drawings are simple and self-explanatory.

18 Figure 1 shows the nature of the rolls produced and the sheets later cut from a roll.

19 Figure 2 illustrates a band-aid type embodiment of the dressing.

20 Figure 3 illustrates a tubular dispenser that can be used to apply a preformed gel to open wounds.

21 *DESCRIPTION OF THE INVENTION*

22 Natural carbohydrate polymers are extruded in a foam form in the shape of thin sheets. As shown
23 in Figure 1, these sheets may range in thickness from 1/32 inch to over an inch and in width ½
24 inch to 32 inches. As shown in the Figure, these sheets may be cut into various sizes and shapes

1 to provide a wide range of dressings for a variety of wound sizes. These sizes can vary from one
2 to a few inches on the sides of square, or rectangular shapes, to full body or appendage coverings
3 of 1 to a few feet on each side.

4 Subsequent to cutting and sizing, the dressings are packaged antiseptically and made sterile.

5 In application, the wound to be treated is thoroughly cleansed with saline, or a preferred topical
6 agent, and any excess exudates removed and the wound debrided if necessary. An appropriate
7 sized dressing is removed from its sterile package and placed over the wound. Larger sized
8 dressings can be reduced in size to effectively match the area of the wound exposure. Upon

9 contact with the moisture on the wound tissue the foam absorbs fluid from the from the wound
10 turning into a gel-like form creating a protective barrier that provides a moist environment for

11 healing, absorbs drainage, exhibits chemo tactic action and provides topical nutrients. The

12 hydrophilic nature can be controlled by addition of biodegradable polyester (BASF). Upon

13 removal, the dressing can be easily and rapidly dissolved by flushing with water and disposed of
14 in a conventional drain.

15 In one embodiment of the invention, the biopolymer is composed of cornstarch polymerized with
16 the assistance of an agent, such as poly vinyl alcohol (PVA). Other types of starch, such as
17 potato, wheat, rice, etc. may be used as well as other polymerizing agents, such as poly ethylene
18 glycol (PEG), poly propylene glycol (PPG), or one of several natural gums.

19 In a preferred embodiment, the starch used is a high amylose cornstarch (National Starch)
20 extruded in flat sheet forms in a process using PVA as the polymerizing agent in a formulation
21 appropriate to our needs; 3% water /90% starch/7% PVA.

22 In another embodiment as shown in Figure 2, the dressings are small and backed by an adhesive
23 tape creating a novel band-aid type bandage that will provide the advantages of the biopolymer
24 dressing to these applications. In a preferred embodiment, packaging is accomplished with

commercial packaging wrappers and sterilization of the packaged dressing is accomplished by gamma radiation at levels sufficient for effective sterilization.

In normal situations adequate moisture is present in the wound to convert the polymer foam to the functioning gel. In situations where the natural moisture of a wound is very small, moisturizing the dressing with sterile saline or other agent prior to application may be required for convenience in fitting the dressing onto the wound site. In another embodiment of the invention, the starch foam dressing can be moistened to the point of a viscous fluid and applied to wound sites by dipping from an open container or extrusion from a flexible tube, as shown in Figure 3. In another embodiment of the invention, the moisturizing agent is a pure water solution of nano-crystalline silver accomplishing both the role of hydrating the resulting gel and acting as a bactericide.

Wounds amenable for treatment with these dressings include acute abrasions, lacerations, burns, stage 2–4 pressure ulcers, diabetic ulcers, venous stasis ulcers, arterial ulcers, donor sites of skin grafts, post surgical incisions, appropriate dental applications and external wounds due to trauma.

SUMMARY OF THE ADVANTAGES OF THE INVENTION

The advantageous features of this invention include effective linear wicking and the minimizing of pain and discomfort upon application and removal of the dressing. The gels created are non-toxic locally and systemically. The gel controls odors, decreases purulent exudates and are not absorbed systematically. The starch foams used are amenable to serve as vehicle for transport and delivery of amino acids, ascorbic acid and other nutrients; enzymatic debriders such as bromolin, and pupain; buffering compounds for pH regulation; and antibiotics, analgesics, bactericides and other compounds for treatment. Where appropriate, scented aromatics can also